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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,800	01/15/2002	Betty Rozier	TBA	7638

7590

06/02/2004

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EXAMINER

ODLAND, KATHRYN P

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/046,800	<b>Applicant(s)</b> ROZIER ET AL.	
	<b>Examiner</b> Kathryn Odland	<b>Art Unit</b> 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 2-30 and 37-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>23 April 2002</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 2-30 and 38-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the paper dated May 5, 2004. Further claim 37 is not consistent with the elected species and has also been withdrawn from consideration.

### ***Information Disclosure Statement***

Citations 17 and 18 of the IDS filed April 23, 2002 have not been initialed for a date has not been provided for these references.

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 31. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Grant in US Patent No. 5,413,120.

Regarding claim 1, Grant discloses a site guard having a hollow member having a base (such as 16 with associated components), *the base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* (such as with or without 14); at least one fabric connector (such as 48, 40, etc) affixed to the hollow member; means (via Velcro® and associated components and slits) for affixing the hollow member to the at least one fabric connector; and means (via Velcro®) for closing the fabric connector on the patient, as recited in columns 2-4 and seen in figures 1-3. That shown in italics above is considered functional language. Nonetheless, the device of Grant performs and is capable of performing the function.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darling in US Patent No. 5,076,289 in view of Grant in US Patent No. 5,413,120.

Regarding claim 1, Darling discloses a site guard having at least one fabric connector (shown generally at 10); a pad (11); and means (via Velcro®) for closing the

fabric connector on the patient, as recited in columns 2-4 and seen in figures 1-2F.

However, Darling does not show a hollow member having a base, the *base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* where the fabric member is affixed to the hollow member and means for affixing the hollow member to have at least one fabric connector. On the other hand, Grant teaches a hollow member (such as 14). Therefore, it would be obvious to one with ordinary skill in the art to replace the pad (11) of Darling with a hollow member for the purpose of having the IV site closer to the hand while maintaining proper security. This combination would yield a *base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover* where the fabric member is affixed to the hollow member and means for affixing the hollow member to have at least one fabric connector. Further, that shown in italics is considered functional language. Nonetheless, the combination would be capable of performing the function.

Regarding claim 31, Darling as modified by Grant discloses that as applied to claim 1, as well as, at least one fabric connector further having at least one opening (13, 14) to accommodate various body parts, as seen in figures 1-2F.

Regarding claim 32, Darling as modified by Grant discloses that as applied to claim 31, as well as, at least one fabric connector having a first opening and a second opening configured to ambidextrously accommodate one or more digits, as seen in figures 1-2F.

Regarding claim 33, Darling as modified by Grant discloses that as applied to claim 32, as well as, a first opening that is configured to receive the right thumb and the second opening is configured to receive the left thumb, wherein either thumb can be inserted in the device.

Regarding claim 34, Darling as modified by Grant discloses that as applied to claim 1, as well as, a Velcro ONE-WRAP strap, and/or combinations of any of the foregoing, as recited in columns 2-4.

Regarding claim 35, Darling as modified by Grant discloses that as applied to claim 34. Further, this combination would yield a Velcro ONE-WRAP strap that affixes to affixing means on the sidewall of the hollow member.

Regarding claim 36, Darling as modified by Grant discloses that as applied to claim 34, as well as, at least one opening to accommodate various body parts, as recited in column 2-4 and seen in figures 1-2F. Further, the tubular mesh is considered an equivalent to a Velcro ONE-WRAP.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 31, 34, 35, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 12, and 23 of U.S. Patent No. 6,526,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter.

### ***Conclusion***

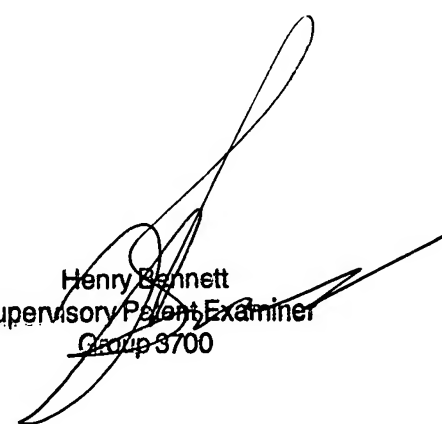
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 5,682,905 and US Patent No. 4,919,150.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO



Henry Bennett  
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